



# UNITED STATES PATENT AND TRADEMARK OFFICE

*cl*  
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/677,501

10/02/2003

David Lauffer

VPI/98-21 DIV US

8260

27916

7590

08/01/2006

VERTEX PHARMACEUTICALS INC.  
130 WAVERLY STREET  
CAMBRIDGE, MA 02139-4242

EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/677,501

Applicant(s)

LAUFFER ET AL.

Examiner

Celia Chang

Art Unit

1625

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

Art Unit: 1625

### DETAILED ACTION

1. Claims 1-24 are in the case. Please note that there is no claim 14, therefore, claims 1-13, 15-25 have been renumbered as claims 1-24 per Rule 26.

2. *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 9-10, drawn to E is pyridyl compounds, classified in class 546, subclass various, depending on species election. If this group is elected, a single disclosed species is also required. Generic claims 1-8, 11 reading on the elected compounds can be prosecuted with the election.
- II. Claims 1-8, 11, drawn to remaining compounds, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- III. Claims 12-14, drawn to multiple active ingredient composition, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single multiple ingredient composition is also required with a single disclosed compound, and every element of the
- IV. ~~Claims 15-24, drawn to~~ <sup>Claims 15-24, drawn to</sup> method of treating patient or ex vivo cell with combination of compound and other therapeutic agents, classified in class various, subclass various depending on species election. If this group is elected, a further election of a single combination with a single disclosed compound and every other ingredient named for the treatment of a single disease or cell is also required.

The inventions are independent or distinct, each from the other because:

The compounds of groups I and II differ in elements and bonding arrangement to such an extent that a reference anticipating compounds of one group would not render the other group obvious. The invention of groups III or IV are unrelated to compound per se of groups

Art Unit: 1625

I or II because patentability of group III depends on the explicit elements of the multiple active ingredient and there quantitative relationship while the patentability of group IV depends on elements of therapeutic combination and their sequence of dosage of administration. The search for the independent and distinct inventions are not co-extensive and separate searches and examination must be conducted.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as well as required a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a group or invention and an election of species to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) ~~of the inventions~~. If the inventions are not patentable, then there could have been no patentability of all the inventions because the compounds of group II have been on market see i.e. CA 2005:4150877.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

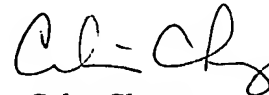
Art Unit: 1625

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*July 27, 2006*

  
*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*